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TITLE: PROSPECTIVE COLLECTION AND BANKING OF LYMPHOCYTES AND CLINICAL DATA ON HIV INFECTED INDIVIDUAL TAKING ANTIRETROVIRAL AGENTS

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Banking of lymphocytes and collection of clinical data is successfully progressing with a total of 645 patients currently enrolled, 5700 separate data collection times and over 14,000 specimens banked for serum and/or lymphocytes. A poster presentation entitled, "The Duration of Clinical Stabilization with Azt Therapy", D.L. Mayers, L.I. Gardner, R. Harris, R. Pomeranz, D. Cohn, and the Military Medical Consortium for Applied Retroviral Research was accepted for the International HIV conference. The data for this poster was based on analysis of the clinical information obtained from this study.

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FOREWORD

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x N/A For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45 CFR 46.

_____In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

_____In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

x N/A In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

6-1-93

Principal Investigator's Signature Date

Supplementary Notes 92MM2549

Banking of lymphocytes and collection of clinical data is successfully progressing with a total 645 patients currently enrolled, 5700 separate data collection times and over 14,000 specimens banked for serum and/or lymphocytes. A poster presentation entitled "THE DURATION OF CLINICAL STABILIZATION WITH AZT THERAPY " D.L. Mayers, L.I. Gardner, R. Harris, R. Pomeranz, D. Cohn, and the Military Medical Consortium for Applied Retroviral Research was accepted for the International HIV conference. The data for this poster was based on analysis of the clinical information obtained from this study.

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Abstract

THE DURATION OF CLINICAL STABILIZATION WITH AZT THERAPY

S.H. Harrison, D.L. Mayers, L.I. Gardner, R. Harris, R. Pomerantz, D. Cohn, et al., Military Medical Consortium for Applied Retroviral Research, Rockville, Maryland, United States.

Objective: To determine the rate of clinical progression of HIV disease in patients (pts) who received AZT therapy stratified by the Walter Reed stage (WR) at the time of initiation of therapy.
Methods: 523 HIV-positive pts are followed with serial clinical evaluations at 3 to 6 month intervals. We performed a residence time analysis of the time the patients spent in each WR stage stratified by the WR stage at initiation of AZT therapy.
Results: Table 1. Clinical Progression on AZT Therapy.

WR Stage at Initiation of AZT	Time in Stage WR1/WR2 M	m	N	Time in Stage WR3/WR4 M	m	N	Time in Stage WR5 M	m	N	Time in Stage WR6 (AIDS) M	m	N
No AZT	680	502	116	470	267	79	370	363	9	709	370	6
WR1/WR2	143	112	26	420	316	28	405	405	1	n.a.	n.a.	0
WR3/WR4	346	260	28	739	674	88	206	130	16	216	216	1
WR5	305	242	30	373	359	68	531	466	25	472	383	8
WR6 (AIDS)	222	253	6	451	335	9	159	128	12	704	755	6

*M = mean (days), m = median (days), N = number of patients

Conclusions: The efficacy of AZT to delay clinical disease progression is of limited duration lasting approximately 600 days for patients with > 400 CD4 cells (WR1/2) and approximately 300 days for patients with < 400 CD4 cells (WR3-6). Subsequent clinical progression occurs at similar rates in AZT-treated and AZT-naive populations by an intention to treat analysis.

ANNUAL REPORT

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3. Reporting Period from: 1 April 1992 to: 31 March 1993

4. P.I.: Richard Harris, LTC, MS 5. Phone #: (303) 361-4042 /DSN 943-4042

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Aurora, CO 80045-5001

7. Project Title: Prospective Collection and Banking of Lymphocytes and Clinical Data on HIV Infected Individuals Taking Antiretroviral Agents. FAMC Protocol # 91/300

8. Current Staff, with percentage of effort on each project:

Richard Harris, LTC, MS	
Erin Palestro, R.N.	100%

9. MIPR Expenditures to date:

Personnel	$ 38,615.	Supplies	$172,561.
Travel	$ 17,114.	Other	$ 2,070.
Equipment	$ 5,991.	Contracts	$ 3,482.

Total $239,833.